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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,866	09/19/2001	Gary M. Fox	00,759-A	9863

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EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,866	FOX ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/23/04* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *01232004* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-58 are pending.

2. As noted in the attached Interview Summary, the instant Restriction Requirement corrects errors in the Restriction Requirement mailed 9/26/03. Accordingly, the Restriction Requirement mailed 9/26/03 is hereby VACATED. A new Restriction Requirement follows.

Restriction Requirement

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-8, 10-11, 43-45 and 57-58, drawn to an isolated nucleic acid comprising SEQ ID NO:1 and variants thereof; vectors, host cells, and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

II. Claims 9, 13-17, 37-42, 46-47, 56, drawn to a polypeptide comprising SEQ ID NO:2, variants thereof, compositions thereof, and fusion proteins comprising said polypeptides; classified in Class 530, subclasses 350 and 387.3 and Class 424, subclass 185.1.

III. Claims 12, 51-52, drawn to a processing for determining whether a compound binds to a B7-L polypeptide and/or inhibits B7-L polypeptide activity or production by an *in vitro* assay, classified in Class 435, subclass 7.21.

IV. Claims 18-32, 34-35, drawn to selective binding agent that binds a B7-L polypeptide and hybridomas producing, classified in Class 530, subclass 388.22 and Class 435, subclass 334.

V. Claims 33, drawn to a method of treating, preventing or ameliorating a B7-L polypeptide related disease by administering a binding agent, classified in Class 424, subclass 143.1.

VI. Claims 36, drawn to a method of detecting or quantitating a B7-L polypeptide with an antibody, classified in Class 435, subclass 7.1.

VII. Claims 48, drawn to a method of treating, preventing or ameliorating a medical condition by administering a B7-L polypeptide, classified in Class 514, subclass 885.

VIII. Claim 49, drawn to a method of diagnosing a pathological condition by determining the presence of a B7-L polypeptide, classified in Class 435, subclass 7.1.

IX. Claim 50, drawn to a device comprising a membrane and cells that secrete a B7-L polypeptide, classified in Class 424, subclass 812.

X. Claim 53, drawn to methods of modulating B7-L polypeptide levels in an animal by administering an encoding nucleic acid, classified in Class 536, subclass 44.

XI. Claim 54, drawn to a non-human transgenic animal comprising a B7-L nucleic acid, classified in Class 800, subclass 13.

XII. Claim 55, a process of determining whether a compound inhibits B7-L polypeptide activity or production by exposing a B7-L transgenic animal to the compound, classified in Class 800, subclass 3.

The Inventions are distinct, each from the other because:

4. Groups I, II, IV, IX and XI are different products. Nucleic acids, polypeptides, agents that bind the polypeptides, devices comprising implantable membranes and transgenic animals each differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.

6. Groups III, V-VIII, X and XII are different methods. Each method differs with respect to one or more of the ingredients, method steps, and endpoints of the method; therefore, each method is patentably distinct.

7. Groups (I and X) (II and III/VII), (IV and V/VI/VIII) and (XI and XII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case:
the nucleic acid of Group I can be used in a method of detecting the DNA in a sample, in addition to the method of modulating levels of the encoded protein in an animal;
the protein of Group II can be used as an immunogen to produce antibodies, in addition to the methods of treating recited;
the antibody of Group IV can be used for affinity purification, in addition to the methods of treating and detecting recited;
the transgenic animal can be used to study the effect of protein expression, in addition to the method of identifying inhibitors as recited.

8. Groups IV and III/XII are related as products and method of identifying said products. However, the method steps do not define the structure of the claimed products. Therefore, they are patentably distinct

9. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search, which would not be completely co-extensive. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (571) 272-0848. The examiner can normally be reached Monday from 8:30 to 5:00, and Tuesday/Thursday from 10:00 to 4:00. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (571) 272-0841. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for before Final submissions is (703) 872-9306.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
January 23, 2004

Phillip Gambel
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PRIMARY EXAMINER
TECH CENTER 1600
1/23/04